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EXAMINER

MATTHEWS, WILLIAM H

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/642,513
Filing Date: August 15, 2003
Appellant(s): OSBORNE ET AL.

Jason Shigelone
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 29, 2011 appealing from the Office action mailed June 22, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The present application was previously appealed on November 14, 2007 and decided by the Board on October 14, 2009.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 45,46,48-50,53,58,60-62 stand rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

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maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,800,526	ANDERSON ET AL	9-1998
2001/0027339	BOATMAN ET AL	10-2001

(9) Grounds of Rejection

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 45,46,48-50,53,58, and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. USPN 5,800,526 ("Anderson") in view of Boatman et al. USPN 2001/0027339 ("Boatman").

Anderson discloses a stent comprising barbs 20 attached to arches 18 of struts in figures 1-7, wherein the stent may be machined from a flat sheet of metal via laser cutting or chemical etching. Figures 4-5 show the stent in the unexpanded form with barbs 20 at the apex of each arch 18. The arch 18 comprises a bend and two struts as claimed. Figures 6-7 show the stent in the expanded state such that arches 18 bend outwardly, thereby directing the barbs to face outwardly at an angle generally transverse or acute to the longitudinal axis:

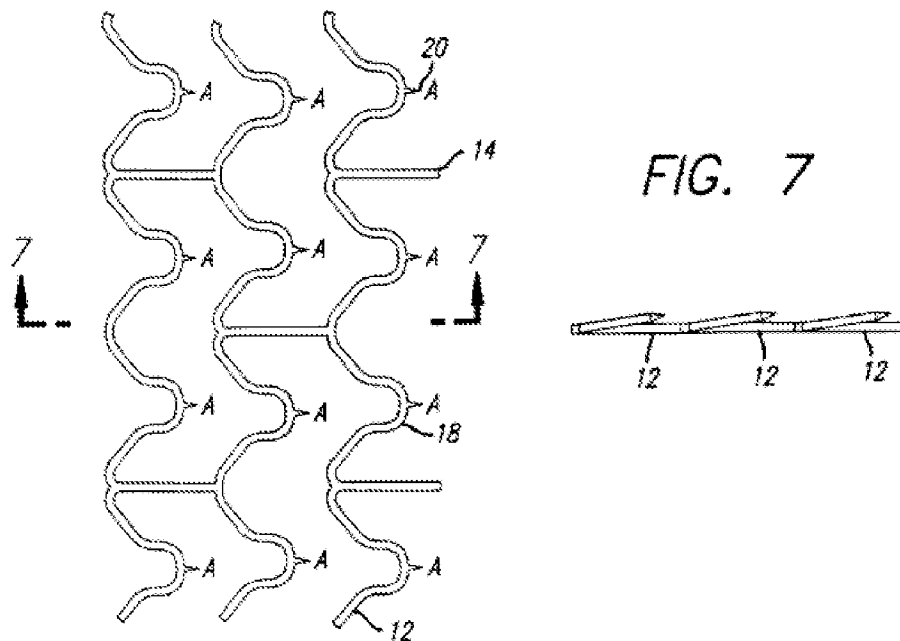


FIG. 6

Column 6, lines 41-58 further describe outwardly bent arches 18 with barbs 20 disposed at the ends of the arches 18. The arches are described as facing outwardly in the expanded state due to rotation of rings 12 during expansion. Anderson thus appears to teach barbs unbent with respect to the stent struts. Anderson further teaches stent material may be removed at selective locations near the barbs to yield desired bending of the stent shown in figures 1-7 (see column 9, lines 16-26). However, Anderson fails to explicitly disclose that only the arches 18 bend, and the barbs do not bend.

Boatman teaches stents are preferably designed to provide bending over only certain curvilinear struts while other sections of the stent do not deform in order to enhance the fatigue life of the stent. See paragraphs 0024, 0081, and 0084.

Furthermore, it would have been apparent to one of ordinary skill in the art to provide

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the greatest fatigue life at the thinner barb junctions of a stent in order to prevent fracture and release of the barbs into the bloodstream.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure the barbs in Anderson are free of unnecessary bending stresses by removing material only along the thicker curvilinear struts 12 such that the arches 18 bend outwardly to direct the barbs 20 to face outwardly (as is shown in figure 7 of Anderson and described at column 6 lines 41-58). The motivation being to enhance the stent's fatigue life as taught by Boatman, and to reduce the possibility of fracture at the barb-strut junction.

With further respect to claims 53, 58 and 60-62, Anderson describe a graft in connection with the stent meeting the limitation of a stent affixed to a substantially cannular body (claim 58) or endoluminal prosthesis (claim 53).

(10) Response to Argument

In Section (A)(1), Appellant addresses the previous BPAI opinion in which the rejection over Anderson as *anticipating* the claimed invention was reversed. Appellant acknowledges that the Board stated “the barbs 20 of Anderson are not necessarily unbent with respect to the wire.” However, Appellant failed to acknowledge the Board’s statement that “both situations are equally probably” (referring to the situations of only the wire 18 or both the wire 18 and barb 20 bending). See BPAI decision, page 5.

At Section (A)(2), Appellant cites portions of Anderson (column 8 lines 17-19) describing a desire for uniform radial expansion of the stent 10 without substantial out-of-plane twisting, and suggests this passage contradicts the disclosed (column 6, lines

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41-58) and depicted (Figures 6-7) outward rotation of arches 18. However, Examiner respectfully points to column 7 lines 31-59, and particularly lines 51-56, which clearly describe the function of interconnections 14 as limiting out of plane twisting.

Furthermore, “twisting of stent 10” relates to a torsional force about the longitudinal axis of the stent, and examiner believes the Board erred in suggesting that outward rotation of arches 18 (i.e. a radial force) contradicts the desire to reduce “out of plane twisting of the stent 10”. Interconnections 14 between cylindrical rings 12, and being aligned in the longitudinal direction, serve to maintain the rotational position of each cylindrical ring 12 relative to one another during delivery and expansion and thus provide for a uniform radial expansion of the stent. See column 7 line 60 through column 8 lines 41. Thus the preferred feature of limiting out of plane twisting of the stent should not be considered as teaching away from the outward rotation of arches 18 with barbs 20 disposed thereon.

At Section (B)(1)(a), Appellant argues the Examiner relies solely on Figure 7 and ignores the disclosure in Anderson at column 9 lines 16-26 which describes “barbs will bend outwardly when the stent is expanded”. Initially, Examiner notes column 9 lines 16-26 describes a particular step etching process which “can be used” (lines 18-19), and is not necessarily required. Furthermore, Examiner’s rejection relies upon the express disclosure at column 6 lines 16-63 which describes the stent of Figures 1-7 as having arches 18 rotate outwardly (i.e. bend) to direct the barbs 20 in an outward facing direction. Column 6 of Anderson (emphasis added):

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valleys are different. Attachment elements or anchors 20, shown in FIG. 1 in the form of barbs, can be provided on the ends of a plurality of the outwardly facing arches of valleys 18 in the rings that rotate outwardly when the stent is expanded, to engage with the aortic wall when the stent is deployed, so that each of a plurality of cylindrical elements has at least one barb that faces partially outwardly when the multi-anchor stent is in an expanded configuration for attaching the stent to the body lumen. In a currently preferred embodiment, as is illustrated in FIG. 1, each of the cylindrical elements has a plurality of barbs that face partially outwardly when the multi-anchor stent is in an expanded configuration for attaching the stent to the body lumen. As is shown in FIG. 1, the configuration of the barbs is preferably such that a barb is placed on each outwardly facing arch of the valleys 18, so that in a currently preferred embodiment, the stent currently has eight valleys per ring, providing eight anchors per ring.

Appellant further cites Figure 7 as lacking any evidence of the nature of the connection between the barbs 20, arches 18, and rings 12. However, Appellant fails to address the disclosure of column 6 cited above. Examiner maintains column 6 and Figures 6-7 of Anderson provide a clear suggestion for arches that rotate or bend outwardly in order to point the barbs disposed thereon in an outward direction without bending the barbs themselves.

At Section (B)(1)(b), Appellant argues that Anderson's disclosure at column 3 of "a plurality of barbs throughout the entire circumference of the stent...so that exact placement of the anchors is less critical." somehow suggests Anderson's barbs point in an **arbitrary, undetermined direction**. Examiner disagrees that the circumferential positioning of the barb anchors relates in any manner to the direction in which the barbs point. Examiner maintains that Anderson teaches barbs that are configured to point in an outward direction in the expanded state for engaging tissue. As the stent is

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designed and known to perform in this manner, the barbs of Anderson may be described as pointing in a predetermined direction when in the expanded state.

At Sections (B)(2) and (B)(3), Appellant argues that the Examiner fails to contend Boatman discloses both a stent with an integral barb that is unbent or barbs that point in a predetermined direction. Examiner agrees. Examiner cited Boatman in order to establish that fatigue life of stent portions (due to bending) is a well known issue in the stent arts since stents undergo cyclical stress in vasculature, and furthermore stent artisans possess the technical knowledge to design portions of stents that do and do not deform during expansion in order to enhance fatigue life (see Boatman, paragraph 0084). Anderson provides integral barbs and barbs that point in a predetermined direction, and further suggests the barbs are unbent with respect to the stent wire arch 18. Thus Boatman provides motivation to ensure the stent is engineered to provide an unbent barb with enhanced fatigue life since it has not been bent.

Appellant further suggests that Boatman teaches away from the proposed modification to Anderson's stent (Brief, page 18, first paragraph). Examiner disagrees. Boatman's statement of distributing forces over plural struts does not teach away from the pertinent teachings relied upon in the rejection.

Appellant further argues that the proposed modification to Anderson "runs counter to the Anderson specification" since column 9 lines 16-22 describe removing material in the area of the barbs so that the barbs will bend outwardly when the stent is expanded. Examiner disagrees. The rejection suggests removing material from the arches with barbs thereon, which is still an "area of the barbs" since arches without

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barbs would not be within a "barb area". Furthermore, Examiner maintains the description at column 9 should be read in conjunction with column 6 which clarifies that **the arches rotate outwardly to direct the barbs outward**. Thus the passage cited at column 9, while literally stating the "removing portions of material so that the barbs will bend outwardly", does not explicitly require removing the material of the barbs.

Examiner maintains the teachings of Anderson reasonably suggest the removed material could be at the arches since it is the arches that are designed to rotate or bend outwardly, and the arches are in the "area of the barbs".

Regarding Section (B)(4), Examiner maintains the combination of Anderson and Boatman renders obvious all of the limitations of claims 45,46,48-50,53,58, and 60-62 as described above.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/William H. Matthews/

Primary Examiner, Art Unit 3774

Conferees:

/DAVID ISABELLA/

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/Thomas C. Barrett/

Supervisory Patent Examiner, Art Unit 3775